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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,283	08/27/2001	Gust H. Bardy	032580.0003.UTL	8060

22440 7590 07/22/2003

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EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	10

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,283	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-150* is/are pending in the application.

4a) Of the above claim(s) *3,47-51,60,108-112 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-46,52-59,61-107,113-115,117-142,145,147,149 and 150* is/are rejected.

7)☒ Claim(s) *143-144,146,148* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/17/02* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species III in Paper No. 8 is acknowledged.

2. Claims 3, 47-51, 60, 108-112, and 116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Drawings

3. The drawings are objected to because in Figure 23 B element number 228 is missing and not shown as it is in Fig. 23A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 52, 56-57, and 146 are objected to because of the following informalities:

Claim 52 recites "the distal housing member extending *proximally* from the main housing member"; while claim 64 recites "the distal housing member further comprises a shoulder region, wherein the shoulder region extends *distally* from the main housing member". These claims are inconsistent with each other. The examiner suggests changing claim 52 to read –the distal housing member extending *distally* from the main housing member.

Claims 56-57 each recite the limitation "proximal housing member". The examiner suggests changing the claim to recite "distal housing member" to be consistent with claim 52.

Claim 146 recites the limitation "inframmary". The examiner suggests changing the claim to recite "inframammary". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22, and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 22 and 85 utilize the language "and mixtures thereof" which render the respective claims indefinite, since it is unclear what is to be covered within the scope of "and mixtures thereof".

DETAILED ACTION

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-2, 4, 14, 16-25, 31, 37-40, 42-43, are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574). Hauser et al. shows a ICD having a housing comprising a proximal end and a distal end, where the width of the distal end (top end) is less than the proximal end (bottom end); an electrical circuit (18) within the housing and an electrode (14,

14', 52, 62, 64, 66, 80) located on the housing and electrically coupled to the electrical circuit (Figs. 1, 3, 8, and 11).

Regarding claim 2, Hauser shows at least a portion of the distal end (top end) is rounded ((Figs. 1, 3, 8, and 11).

With respect to claim 4, Hauser et al. shows at least a portion of the proximal end (bottom end) is rounded (Figs. 1, 3, 8, and 11).

Regarding claim 14, Hauser et al. shows the housing is bilaterally symmetrical along the housing's length (Figs. 1, 3, 8, and 11). The examiner points out that if a plane was located in regards to half of the depth, and along the length of the ICD, it is bilaterally symmetrical along the housings length.

With respect to claim 16, Hauser et al shows the proximal end of the housing is contiguous with the distal end of the housing (Figs. 1, 3, 8, and 11).

Regarding claims 17-18, Hauser et al. shows at least a portion (70) of the housing comprises an electrically nonconductive or insulated material (Col. 6, lines 54-60).

With respect to claim 19, Hauser et al shows at least a portion (70) of the housing comprises a ceramic material (Col. 6, lines 54-60).

Regarding claim 20, Hauser et al. shows the housing comprises a titanium alloy (Col. 6, lines 48-49).

With respect to claims 21-22, Hauser et al shows the housing comprises a polymeric material comprising silicone (Col. 4, lines 48-49; Col. 6, lines 64-65).

Regarding claims 23-24, Hauser et al shows at least a portion of the housing is substantially non planar (the rounded ends of the housing) and at least a portion of the housing is substantially planar (the sides of the housing) (Figs. 1, 3, 8, and 11).

With respect to claims 25 and 31, Hauser et al shows the electrical circuit can provide cardioversion defibrillation (Abs) and the electrode (14, 14', 52, 62, 64, 66, 80) can emit an energy for shocking the patient's heart (Col. 2, lines 29-34).

Regarding claims 37-38, Hauser et al. shows the electrode can receive sensory information (Col. 7, lines 9-15).

With respect to claim 39, Hauser et al. shows at least a portion of the electrode is non planar (Figs. 1, 3, 8, and 11).

Regarding claim 40, Hauser et al. shows the electrode (14) is substantially circular in shape. (Figs. 12-14).

With respect to claim 42, Hauser et al. shows the electrode (14') is substantially square in shape. (Fig. 3).

Regarding claim 43, Hauser et al. shows the electrode (62, 64) is substantially rectangular in shape. (Fig. 11).

9. Claims 52, 55-57, 59, 61, 71, 75-78, 82-83, 86, 92, 100 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams (5,601,607). Adams shows a duckbill-shaped ICD having a housing comprising a main housing member (74) having a length, a width and a depth; a distal housing member (76, 84) extending distally from the main housing member wherein the distal housing member has a length, a width and a depth; an electrical circuit (92) located within

the main housing member; and an electrode (76, 84) electrically coupled to the electrical circuit and located on the distal housing member (Figs. 7-8).

The term "duckbill-shaped" recited in the preamble has not been interpreted by the examiner to impart any additional structural limitations to the claim beyond those structural limitations recited in the body of the claim. See *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

Regarding claim 55, Adams shows the implantable cardioverter is substantially bilaterally symmetrical along the length. The examiner points out that if a plane was located in regards to half of the depth, and along the length of the ICD, it is bilaterally symmetrical along the housings length.

With respect to claims 56-57, Adams shows the distal housing member is in fluid communication or contiguous with the main housing member (Figs. 7-8).

Regarding claim 59, Adams shows the distal housing member (76, 84) has a distal end and at least a portion of the distal end of the distal housing member is curved (Figs. 7-8).

With respect to claim 61, Adams shows the main housing member (74) has a proximal end and at least a portion of the proximal end of the main housing member is curved (Figs. 7-8).

Regarding claim 71, Adams shows the depth of the distal housing member (76, 84) is less than the depth of the main housing member (74) (Figs. 7-8).

With respect to claims 75-77, Adams shows at least a portion of the distal housing member and at least a portion of the main housing member is substantially non planar (the rounded ends of the distal and main housing members) and at least a portion of the main housing member is substantially planar (the sides of the main housing member) (Figs. 7-8).

Regarding claim 78, Adams shows the distal housing member is substantially bilaterally symmetrical along its length. The examiner points out that if a plane was located in regards to half of the depth, and along the length of the ICD, it is bilaterally symmetrical along the housings length.

With respect to claims 82-83, Adams shows the housing comprises a titanium alloy or stainless steel alloy (Col. 4, lines 7-8).

Regarding claims 86, and 92, Adams shows the electrical circuit can provide cardioversion-defibrillation and the electrode (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Figs. 11-12, 14-18) (Col. 5, line 43-Col. 6, line 45).

With respect to claim 100, Adams shows at least a portion of the electrode is non planar (rounded ends) (Figs. 7-8).

Regarding claim 104, Adams shows the electrode (76, 84) is substantially rectangular in shape (Figs. 7-8).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). Hauser et al. discloses the claimed invention except for the specific dimensions of the housing. It would have been an obvious matter of design choice to form the width of the proximal end and the distal end of the housing to be from 1 cm to 10 cm wide or 2 cm to 5cm

wide, the depth of the proximal end of the housing to be less than 15 mm, the depth of the distal end of the housing to be approximately 1 mm to 15 mm or 1 mm to 3 mm, and the length of the housing is approximately 3 cm to 30 cm long, or 5 cm to 20 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Meltzer (5,645,586). Hauser et al. discloses the claimed invention except for the proximal end of the housing being hinged to the distal end of the housing. Meltzer teaches a housing having hinges between sections of the housing, where the hinges provide the housing the ability to conform to and flex with the implantation site (Col. 2, lines 17-30). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a hinge as Meltzer teaches between the proximal end and the distal end of the housing of Hauser et al. in order to for the housing the ability to conform to the implantation site and flex with the implantation site.

13. Claims 26-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Mower (5,871,506). Hauser et al. discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Mower also teaches that application of monophasic pacing pulses is well known, though it doesn't have the advantages of biphasic pacing pulses (Col. 6, line 23 – Col. 7, line 60). Therefore it would have been obvious to one

with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Hauser et al. since they are well known in the art an the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

14. Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Whigham et al. (4,821,724). Hauser et al. discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Whigham et al. teaches the application of triphasic (i.e. multiphasic) pacing pulses so that reliable sensing of evoked responses can be sensed (Col. 2, line 63-Col. 3, line 1) due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse (Abs). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply triphasic pacing pulses as Whigham et al. teaches with the device of Hauser et al. since the application of triphasic pacing pulses enables reliable sensing of evoked responses due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse.

15. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) and further in view of Ostroff (5,215,081). Hauser et al. is as explained before. Although Hauser et al. fails to specify the desirable ranges shock energy, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the a ranges of shock energies set forth in the

claims, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

16. Claims 41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). Hauser et al. is as explained before. Hauser et al. discloses the claimed invention except for electrode being ellipsoidal, triangular, thumbnail or spade shaped. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shape of the electrode as taught by Hauser et al. with a ellipsoidal, triangular, thumbnail or spade shaped electrode, since applicant has not disclosed that ellipsoidal, triangular, thumbnail or spade shaped electrode provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape electrode such as the square, circular or rectangular electrodes taught by Hauser et al. for applying defibrillation energy.

17. Claims 53-54, 62-63, and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607). Adams discloses the claimed invention except for the specific dimensions of ICD. It would have been an obvious matter of design choice to form the width of the main housing member o be from 3 cm to 30 cm wide or 3 cm to 20cm wide, the depth of the distal housing member to be less than 15 mm, the depth of the main housing member to be approximately 1 mm to 15 mm or 1 mm to 10 mm, and the length of the housing is approximately 5 cm to 20 cm long or less than 30 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

18. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Meltzer (5,645,586). Adams is as explained before. Adams discloses the claimed invention except for the proximal end of the housing being hinged to the distal end of the housing. Meltzer teaches a housing having hinges between sections of the housing, where the hinges provide the housing the ability to conform to and flex with the implantation site (Col. 2, lines 17-30). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a hinge as Meltzer teaches between the proximal end and the distal end of the housing of Adams in order to for the housing the ability to conform to the implantation site and flex with the implantation site.

19. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Laird et al. (6,445,956). Adams is as explained before. Adams discloses the claimed invention except for the distal housing member further comprising a shoulder region extending distally from the main housing member. Attention is directed to Laird et al. which teaches that along with designing implantable device of minimal volume intuitive considerations have led designers to avoid sharp corners on the exterior surface of implantable devices (Col. 1, lines 42-48). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a shoulder region on the distal housing member extending distally from the main housing member in order to avoid sharp corners on the exterior surface of implantable device.

20. Claims 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Laird et al. (6,445,956) as applied to claim 64. Adams and Laird et al. disclose the claimed invention except for the shoulder region having a width less than the width

of the main housing member; the shoulder region width decreasing as the shoulder region extends distally from the main housing member; the shoulder region width decreasing proportionally as the shoulder region extends distally from the main housing member; the distal housing member further comprising a distal head that extends distally from the shoulder region and defines a distal end of the distal housing member; the distal head of the distal housing member has a width less that the width of the shoulder region; or the distal head of the distal housing member has a width greater than the width of the shoulder region of the distal housing member. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the shoulder region and distal housing member as taught by Adams and Laird et al. with the shoulder region having a width less than the width of the main housing member; the shoulder region width decreasing as the shoulder region extends distally from the main housing member; the shoulder region width decreasing proportionally as the shoulder region extends distally from the main housing member; the distal housing member further comprising a distal head that extends distally from the shoulder region and defines a distal end of the distal housing member; the distal head of the distal housing member has a width less that the width of the shoulder region; or the distal head of the distal housing member has a width greater than the width of the shoulder region of the distal housing member, since applicant has not disclosed that these particular shapes provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape of the shoulder region and distal housing member such as the shoulder region and distal housing member taught by Adams and Laird et al. for providing an implantable cardioverter defibrillator housing. A change in shape absent persuasive evidence of the significance of the configuration has been held

to be a matter of obvious design choice to one with ordinary skill in the art. See *In re Dailey,* 357 F.2d 669 (CCPA 1966).

21. Claims 79-80, and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Fayram et al. (5,658,321). Adams is as explained before. Although Adams fails to teach the housing comprises an electrically insulated or non-conductive material, or a polymeric material, attention is directed to Fayram et al. which teaches an ICD that comprises an insulative, nonconductive, silicone polymer. Fayram et al. teaches coating a portion of the housing with silicone provides improved directionality for the defibrillation current. Therefore, it would have obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Adams to include a an electrically insulated or non-conductive material, or a silicone polymeric material as Fayram et al. teaches in order to provide improved directionality for the defibrillation current.

22. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Hassler et al. (5,470,345). Adams is as explained before. Although Adams fails to teach the housing comprises a ceramic material, attention is directed to Hassler et al. which teaches forming implantable medical devices from ceramic. Hassler teaches that the use of ceramics for the implantable medical device enclosure makes the enclosure transparent to RF waves for telemetry purposes. Hassler further teaches that metal enclosures often cause interference during telemetry (Col. 1, lines 19-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form the housing of Adams to comprise ceramic material as Hassler teaches in order to make the enclosure transparent to RF waves for telemetry purposes.

23. Claims 87-89, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Mower (5,871,506). Adams discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Mower also teaches that application of monophasic pacing pulses is well known, though it doesn't have the advantages of biphasic pacing pulses (Col. 6, line 23 – Col. 7, line 60). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Adams since they are well known in the art an the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

24. Claims 88 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Whigham et al. (4,821,724). Adams discloses the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Whigham et al. teaches the application of triphasic (i.e. multiphasic) pacing pulses so that reliable sensing of evoked responses can be sensed (Col. 2, line 63-Col. 3, line 1) due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse (Abs). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply triphasic pacing pulses as Whigham et al. teaches with the device of Adams since the application of triphasic pacing pulses enables reliable sensing of evoked responses due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse.

25. Claims 93-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) and further in view of Ostroff (5,215,081). Adams is as explained before. Although Adams fails to specify the desirable ranges shock energy, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the a ranges of shock energies set forth in the claims, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

26. Claims 98-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Hauser et al. (5,385,574). Adams is as explained before. Although Adams fails to teach the electrode can receive sensory information, attention is directed to Hauser et al which teaches a similar device with housing electrodes that can either be used for defibrillation or sensing (Col. 7, lines 9-15). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to configure the defibrillation electrode of Adams to be able to receive sensory information as Hauser et al teaches in order for the housing electrodes to be used interchangeably.

27. Claims 101-103, 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607). Adams is as explained before. Adams discloses the claimed invention except for electrode being circular, ellipsoidal, square, triangular, thumbnail or spade shaped. It would have been an obvious design choice to one with ordinary skill in the art at the time the

invention was made to modify the shape of the electrode as taught by Adams with a circular, ellipsoidal, square, triangular, thumbnail or spade shaped electrode, since applicant has not disclosed that a circular, ellipsoidal, square, triangular, thumbnail or spade shaped electrode provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any shape electrode such as the rectangular electrode taught by Adams for applying defibrillation energy.

28. Claims 113-115, 117, 127-133, 139, 142, 145, 147, 149, and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338). Adams shows a method of inserting an ICD comprising providing a duckbill-shaped ICD comprising a housing (74,76, 84); an electrical circuit (92) located within the housing; an electrode (76, 84) located on the housing member (Figs. 7-8) and the ICD is configured to maintain the electrode in a predetermined relationship subcutaneously over a patient's ribcage (Fig. 3) (Figs. 7-8). Although Adams fails to specifically teach making a single incision on a patient's thorax and advancing the ICD through the single incision and subcutaneously over a patient's ribcage, attention is directed to Bardy which teaches a similar ICD having an electrode located on the housing that is implanted subcutaneously over the ribcage through a single incision. Bardy teaches that since the housing acts as a defibrillation electrode, a single incision can be made to implant the electrode, compared to systems that require a separate subcutaneous electrode apart from the housing. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to perform the steps of making a single incision on a patient's thorax and advancing the ICD through the single incision an subcutaneously over a patient's ribcage as Bardy teaches to the method of implanting the

duckbilled ICD of Adams since the utilization of a single incision is facilitated by the use of a defibrillation electrode located on the housing and because a single incision is more advantageous than multiple incisions since a single making a single incision would reduces tissue trauma and bleeding.

The term "duckbill-shaped" has not been interpreted by the examiner to impart any additional structural limitations to the claim beyond those structural limitations recited for the structure of the housing.

With respect to claim 114, Adams further shows the housing comprises a proximal end (74) and a distal end (76, 84), where the width of the distal end is less than the proximal end (Figs. 7-8).

Regarding claim 115, Adams shows at least a portion of the distal end (76,84) is rounded (Figs. 7-8).

With respect to claim 117, Adams shows at least a portion of the proximal end (74) is rounded (Figs. 7-8).

Regarding claim 127, Adams shows the housing is bilaterally symmetrical along the housing's length (Figs. 7-8). The examiner points out that if a plane was located in regards to half of the depth, and along the length of the ICD, it is bilaterally symmetrical along the housings length.

With respect to claim 128, Adams shows the proximal end of the housing is contiguous with the distal end of the housing (Figs. 7-8).

Regarding claims 129-130, Adams shows at leas a portion of the housing (74) comprises an electrically insulated or nonconductive material (Figs. 7-8).

With respect to claims 131-132, Adams shows the housing is substantially non planar (the rounded ends of the distal and main housing members) and the housing is substantially planar (the sides of the main housing member) (Figs. 7-8).

Regarding claims 133, and 139, Adams shows the electrical circuit can provide cardioversion-defibrillation and the electrode (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Figs. 11-12, 14-18) (Col. 5, line 43-Col. 6, line 45).

With respect to claim 142, Adams shows at least a portion of the electrode is non planar (rounded edges) (Figs. 7-8).

Regarding claims 145, and 147, Adams shows the ICD is advanced proximate the patient's heart and sternum (Fig. 3)

With respect to claims 149-150, Adams shows the ICD refrains from directly contacting the patient's heart and intrathoracic vessels. (Fig. 3)

29. Claims 118-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338). Adams and Bardy disclose the claimed invention except for the specific dimensions of the housing. It would have been an obvious matter of design choice to form the width of the proximal end and the distal end of the housing to be from 1 cm to 10 cm wide or 2 cm to 5cm wide, the depth of the proximal end of the housing to be less than 15 mm, the depth of the distal end of the housing to be approximately 1 mm to 15 mm or 1 mm to 3 mm, and the length of the housing is approximately 3 cm to 30 cm long, or 5 cm to 20 cm long since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

30. Claims 134-136, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338) as applied to claims 113, and 133 and further in view of Mower (5,871,506). Adams and Bardy disclose the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic (i.e. multiphasic) waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Mower also teaches that application of monophasic pacing pulses is well known, though it doesn't have the advantages of biphasic pacing pulses (Col. 6, line 23 – Col. 7, line 60). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic (i.e. multiphasic) pacing pulses as Mower teaches with the device of Adams and Bardy since they are well known in the art an the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

31. Claims 135, and 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338) as applied to claim 113 and further in view of Whigham et al. (4,821,724). Adams and Bardy disclose the claimed invention except for the setting forth the specific waveforms utilized in cardiac pacing. Whigham et al. teaches the application of triphasic (i.e. multiphasic) pacing pulses so that reliable sensing of evoked responses can be sensed (Col. 2, line 63-Col. 3, line 1) due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse (Abs). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply triphasic pacing pulses as Whigham et al. teaches with the device of Adams and Bardy since the application of

triphasic pacing pulses enables reliable sensing of evoked responses due to the elimination of after potentials due to the charge balancing of the tri-phasic pulse.

32. Claims 140-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,601,607) in view of Bardy (5,292,338) as applied to claim 113 and 139 and further in view of Hauser et al. (5,385,574). Adams and Bardy are as explained before. Although Adams and Bardy fail to teach the electrode can receive sensory information, attention is directed to Hauser et al which teaches a similar device with housing electrodes that can either be used for defibrillation or sensing (Col. 7, lines 9-15). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to configure the defibrillation electrode of the Adams and Bardy device to be able to receive sensory information as Hauser et al teaches in order for the housing electrodes to be used interchangeably.

Allowable Subject Matter

33. Claims 143-144, 146, and 148 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claim 143, the prior art or record fails to teach or suggest a method of inserting an ICD comprising providing a duckbill-shaped ICD comprising an electrode on the housing and where the duckbill-shaped ICD is configured to maintain the electrode in a predetermined relationship subcutaneously over a patient's ribcage; making a single incision on a patient's thorax; advancing the duckbill-shaped ICD through the single incision and subcutaneously over a patient's ribcage in combination with the single incision being made approximately at the level of the cardiac apex.

Regarding claim 144, the prior art or record fails to teach or suggest a method of inserting an ICD comprising providing a duckbill-shaped ICD comprising an electrode on the housing and where the duckbill-shaped ICD is configured to maintain the electrode in a predetermined relationship subcutaneously over a patient's ribcage; making a single incision on a patient's thorax; advancing the duckbill-shaped ICD through the single incision and subcutaneously over a patient's ribcage in combination with the single incision being made approximately in the left anterior axillary line.

With respect to claim 146, the prior art or record fails to teach or suggest a method of inserting an ICD comprising providing a duckbill-shaped ICD comprising an electrode on the housing and where the duckbill-shaped ICD is configured to maintain the electrode in a predetermined relationship subcutaneously over a patient's ribcage; making a single incision on a patient's thorax; advancing the duckbill-shaped ICD through the single incision and subcutaneously over a patient's ribcage in combination with the ICD being advanced medially toward a patient's left inframamary crease.

Regarding claim 148, the prior art or record fails to teach or suggest a method of inserting an ICD comprising providing a duckbill-shaped ICD comprising an electrode on the housing and where the duckbill-shaped ICD is configured to maintain the electrode in a predetermined relationship subcutaneously over a patient's ribcage; making a single incision on a patient's thorax; advancing the duckbill-shaped ICD through the single incision and subcutaneously over a patient's ribcage in combination with the ICD being advanced approximately between a patient's third and twelfth rib.

Conclusion

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sanchez-Zambrano (5,895,414) shows a pacemaker that is implanted over the ribs of a patient. Fenster (5,107,836) shows prior art implantation locations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld
July 7, 2003

KENNEDY SCHAETZLE
PRIMARY EXAMINER
7-11-03